USDA Foreign Agricultural Service
GAIN Report
Global Agriculture Information Network
Template Version 2.09

Voluntary Report - public distribution

Date: 11/20/2006

GAIN Report Number: JA6062

Japan

Food and Agricultural Import Regulations and Standards

New MRLs and Food Additives

2006

Approved by:
Rachel Nelson
U.S. Embassy

Prepared by:
Rachel Nelson

Report Highlights:
Japan intends to approve new MRLs for Boscalid, Flubendiamide and Ofloxacin and to approve two new food additives, R,R,R-α-Tocopheryl Acetate and *all-rac*-α-Tocopheryl Acetate.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Tokyo [JA1]
[JA]

Japan intends to approve new MRLs for the fungcide Boscalid and insecticide Flubendiamide and to make the MRLs for the veterinary drug, Ofloxacin, permanent.

For the two food additives, R,R,R-α-Tocopheryl Acetate and *all-rac*-α-Tocopheryl Acetate, use standards have been established which specify that it will only be permitted for use in foods with health claims and that each target food shall not contain the additive at levels exceeding the equivalent of 150 mg of α-tocopheryl in the recommended daily intake of food.

Some information is given below, but if you would like more details, please send a message and your Fax number to agtokyo@usda.gov.

The deadline for comments directly the Ministry of Health, Labour and Welfare was November 13, however these changes will be submitted to the WTO for an additional comment period sometime in the future. If you have any concerns, please send them as soon as possible directly to agtokyo@usda.gov for possible discussion with the Japanese Government, or for possible inclusion in U.S. comments in the WTO.

Agenda 1. Establishment of Maximum Residue Limits for the Pesticides Boscalid and Flubendiamide in Food

Purpose
This activity is to develop specifications and standards for foods. Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the Minister of Health, Labour, and Welfare may establish residue standards (maximum residue limits: MRLs) for agricultural chemicals (pesticides, feed additives, and veterinary drugs) that may remain in foods. Any food for which standards are established pursuant to the provisions is not permitted to be marketed unless such food complies with the established standards.

On November 29, 2005 the Ministry of Health, Labour and Welfare issued notifications regarding the positive list system for agricultural chemicals in food (Notification Nos. 497, 498, and 499), which became effective on May 29,2006. Basically, chemicals remaining in foods distributed in the Japanese marketplace must meet the residue standards.

Outline of the activity
Boscalid (Fungicide): This chemical is already approved in Japan. The Ministry of Agriculture, Forestry and Fisheries will expand the scope of target crops on which the chemical is permitted for use. In response to MAFF's action, the MHLW will additionally establish MRLs for some crops and revise some of the MRLs which are specified in the Specificatrons and Standards for Food, Food Additives, Etc (see Attachment 1).

Currently, MRLs for this substance appear in the "provisional MRLs list" in the Specifications and Standards for Food, Food Additives, Etc. (Part I "Food," Section A "General Compositional Standards for Food," Item 7) and the "MRLs list" (Item 6 of Section A). By this activity, the MRLs in the "provisional MRLs list" will be deleted and they will be established in the "MRLs list." In addition, some of the MRLs appearing in the "MRLs list" will be modified. "

Flubendiamide (Insecticide): This chemical is not permitted for use in Japan. This time it will be approved by MAFF based on the Agricultural Chemicals Regulation Law. In response to MAFF's action, the MHLW will newly establish MRLs for this chemical (see Attachment 2).

Attachment 1.
Boscalid

Commodity	(draft) MRL	Current MRL
Turnip ,leaves	10	10
Tomato	5	3
Pimiento (sweet peppers)	10	1.2
Unshu orange, pulp	1	
Citrus natsudaidai, whole	10	
Lemon	10	
Orange (including navel orange)	10	
Grapefruit	10	
Lime	10	
Other citrus fruits[1]	10	
Unshu orange, peel	40	2.5
Other spices (except unshuu peel)[2]	2.5	2.5
Other herbs (except spearmint & peppermint)[3]	18	18
Other terrestrial mammals, Muscle (except sheep, horse, and goat)[4]	0.05	0.05
Other terrestrial mammals, Fat (except sheep, horse, and goat)	0.1	0.1
Other terrestrial mammals, Liver (except sheep, horse, and goat)	0.05	0.05
Other terrestrial mammals, Kidney (except sheep, horse and goat)	0.05	0.05
Other terrestrial mammals, Other edible parts[5] (except sheep, horse, and goat)	0.05	0.05

Note
1. "Other citrus fruits" refer to all citrus fruits, except unshu orange (pulp), citrus natsudaidai (pulp), citrus natsudaidai (peels), citrus natsudaidai (whole), lemon, orange (including navel orange), grapefruit, lime and spices.
2. "Other spices" refer to all spices, except horseradish, wasabi (Japanese horseradish) rhizomes, garlic, peppers chili, paprika, ginger, lemon peels, orange peels (including navel orange), yuzu (Chinese citron) peels and sesame seeds.
3. "Other herbs" refer to all herbs, except watercress, nira, parsley stems and leaves, celery stems and leaves.
4. "Other terrestrial mammals" refer to all other terrestrial mammals, except cattle and pig.
5. "Other edible parts" refers to all edible offal, except muscle, fat, liver and kidney. '

Attachment 2.
Flubendiamide (Insecticide)

Commodity	MRL (draft) ppm
Soybeans, dry	0.3
Japanese radish, roots (including radish)	0.03
Japanese radish, leayes (including radish)	10.0
Chinese cabbage	5.0
Cabbaqe	3.0
Lettuce (Cos lettuce, Leaf lettuce)	15.0
Welsh (including leek)	3.0
Tomato	0.7
Apple	1.0
Japanese pear	0.7
Pear	0.7
Peach	0.05
Strawberry	2.0
Tea	40.0

Item 2. Establishment of Standards for the Veterinary Drug Ofloxacin in Food

Purpose
This activity is to develop specifications and standards for foods. Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the Minister of Health, Labour, and Welfare may establish residue standards (maximum residue limits: MRLs) for agricultural chemicals (pesticides, feed additives, and veterinary drugs) that may remain in foods. Any food for which standards are established pursuant to the provisions is not permitted to be marketed unless such food complies with the established standards.

On November 29, 2005 the Ministry of Health, Labour and Welfare issued notifications regarding the positive list system for agricultural chemicals in food (Notification Nos. 497, 498, and 499), which became effective on May 29, 2006. Basically, chemicals remaining in foods distributed in the Japanese marketplace must meet the residue standards.

Outline of the activity
Ofloxacin is already approved under the Agricultural Chemicals Regulation Law as a antibiotic. In response to an application, the Ministry of Agriculture, Forestry and Fisheries has reassessed this drug on the basis of the legal requirement, which provides that reassessment must be conducted every six years after veterinary drugs are once approved. In the wake of reassessment, the MHLW has reviewed the provisional MRLs (see Attachment 3).

The MRLs for the substance, which currently appear only in the "provisional MRLs list" (Item 7 of Section A), will be deleted, and they will be established in the "MRLs list" (Item 6 of Section A).

Attachment 3

Ofloxacin (Synthetic Antibacterials)

Commodity	Draft MRL ppm	Current MRL ppm
Chicken, muscle	0.05	0.05
Chicken, fat	0.05	0.05
Chicken, liver	0.05	0.05
Chicken, kidney	0.05	0.05
Chicken, other edible parts [1]	0.05	0.05

Note
1. "Other edible parts" refers to all edible parts except muscle, fat, liver and kidney.

Agenda 4. Designation of Food Additives (R,R,R-u-Tocopheryl Acetate, all-rac-u-Tocopheryl Acetate)

Purpose
This activity is to newly designate two substances (R,R,R-a-Tocopheryl Acetate, -*all-rac*-a-Tocopheryl Acetate) as authorized fO9d additives.
Under Article 10 of the Food Sanitation Law, food additives may be used or marketed only 'when they are designated by the Minister of Health, Labour and Welfare. Where use standards or specifications are established for additives under Article 11 of the law, those additives may be marketed only when they meet the established standards or specifications.

In response to consultation by the Minister, the Subcommittee on Food Additives under the Food Sanitation Committee under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of the designation of these substances as food additives. The report from the subcommittee is outlined as below.

Outline
The Minister should designate R,R,R-a-Tocopheryl Acetate and *all-rac*-a-Tocopheryl Acetate based on Article 10 of the Food Sanitation Law as food additives not injurious to human health. Under Article 11 of the law, compositional specifications and use standards for these substances should be established. (See Attachments 5 and 6).

Additional Information
The risk assessment progress for food additives that have been proven safe by JECF A (Joint F AO/WHO Expert Committee on Food Additives) and that' are widely used in the world (Attachment 7).

Attachment 5 **R,R,R-a-Tocopheryl Acetate**

Standards for use

R,R,R-α-Tocopheryl Acetate is permitted for use only in foods with health claims. Each target food shall not contain the additive at levels exceeding the equivalent of 150 mg of α-tocopherol in the recommended daily intake of the food.

Compositional Specifications

(2R)-2,5,7,8,-Tetramethyl-2-[(4R,8R)-4,8,12,-trimethyltridecytlchroman-6-yl acetate

Content R,R,R-α-Tocopheryl Acetate contains not less than 96.0-102.0% of R,R,R-α-tocopheryl acetate ($C_{31}H_{52}0_3$) when calculated on the anhydrous basis.

Description It occurs as a colorless to yellow viscous liquid. It is odorless or has a slight characteristic odor.

Identification (1) Dissolve 0.05 g of Determine the infrared absorption spectrum in 10 ml of absolute ethanol, add 2 ml of nitric acid, and heat at about 75°C for 15 minutes. The solution is orange to red. (2) Determine the infrared absorption spectrum of R,R,R-a-Tocopheryl Acetate as directed in the Liquid Film Method under Infrared Spectrophotometry. Compare the obtained spectrum with the Reference Spectrum. Both spectra exhibit absorptions having almost the same intensity at the same wave numbers.